

Notice of Allowability

Application No.

10/758,515

Examiner

Maria B. Marvich, PhD

Applicant(s)

BRAMBILLA ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/22/05.
2. ☒ The allowed claim(s) is/are 2-4, 6 and 7.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/130,061.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

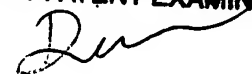
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
- ☒ Examiner's Amendment/Comment
- ☐ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER



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ALLOWANCE

This office action is in response to an amendment filed 8/22/05. Claims 1, 5 and 8-10 have been cancelled. Claim 2 has been amended.

Claims 2-4, 6 and 7 are pending in this application.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

IN THE SPECIFICATION:

The priority data has been amended to read: In the first line of the specification insert

--CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a divisional of copending U.S. Patent Application Serial No. 10/130,061, filed May 15, 2002, now Patent No. 6,841,378, which is a national phase entry of PCT/EP00/00268, filed January 14, 2000, which claims priority to Italian application MI99A000065, filed January 15, 1999. --

On page 6, line 9, delete the term "Zygosaccharomyce ailii" following the phrase "host cells:" and insert --Zygosaccharomyces bailii--.

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On page 6, line 24 delete the phrase “(<http://www.ncbi.nlm.nih.gov/>)”.

On page 7, line 27, delete the word “5rouxi” prior to the phrase “for the production of” and insert --rouxii--

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the present invention advances the prior art by design of a process for production of homologous or heterologous proteins using Zygosaccharomyces bailii transformed with an expression vector comprising an Autonomously Replicating Sequence (ARS) from S. cerevisiae and a centromeric sequence (CEN) from S. cerevisiae or Z. bailii. The method of the invention is most similar to the invention of Gilbert et al, US 2002/0034805 or Sjoberg et al (6,500,661). The difference between the instant invention and the prior art is that Gilbert et al and Sjoberg et al are directed toward methods of producing specific proteins to which end applicants contemplate use of Z. bailii to generate the protein. However, applicants are the first to characterize the requirements of Z. bailii necessary for protein expression. Specifically, applicants identify vector requirements necessary for production and recovery of recombinant proteins (see page 9, line 20- page 10, line 26). Applicants teach that at the time of filing, nothing had been published regarding expression of recombinant proteins from this yeast (page 8, line 18-19). However, applicants consider Z. bailii to be a good organism for growth of recombinant proteins as it displays an exceptional resistance to stress, it can grow in media with low water availability, high hydrostatic pressure and high temperatures, it tolerates high sugar concentrations and acid

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environments, high preservative concentrations (page 6, line 8-21). Hence applicants have characterized the requirements for successful protein production using this strain.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claim 2-4, 6 and 7 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
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October 26, 2005

**DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER**